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Do cigarette health warning labels comply with requirements: A 14-country study☆

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ABSTRACT

The Framework Convention on Tobacco Control, a global health treaty ratified by over 175 countries, calls on countries to ensure that tobacco packages carry health warning labels (HWLs) describing the harmful effects of tobacco use. We assessed the extent of compliance with 14 countries' HWL requirements. Unique cigarette packs were purchased in 2013 using a systematic protocol in 12 distinct neighborhoods within three of the ten most populous cities in the 14 low- and middle-income countries with the greatest number (count) of smokers. HWL compliance codebooks were developed for each country based on the details of country-specific HWL requirements, with up to four common compliance indicators assessed for each country (location, size, label elements, text size). Packs (n = 1859) were double coded for compliance. Compliance was examined by country and pack characteristics, including parent company and brand family. Overall, 72% of coded cigarette packs were compliant with all relevant compliance indicators, ranging from 17% in the Philippines to 94% in Mexico. Compliance was highest for location of the warning (ranging from 75%–100%) and lowest for warning size (ranging from 46%–99%). Compliance was higher for packs bought in high SES neighborhoods, and varied by parent company and brand family. This multi-country study found at least one pack in every country – and many packs in some countries – that were not compliant with key requirements for health warning labels in the country of purchase. Non-compliance may be exacerbating health disparities. Tobacco companies should be held accountable for complying with country HWL requirements.

1. Introduction

Health warning labels (HWLs) on tobacco packs are important for communicating the dangers of smoking, particularly given their extensive reach; HWLs may be viewed by pack-a-day smokers over 7000 times a year (Hammond, 2011). Article 11 of the World Health Organization's (WHO) Framework Convention on Tobacco Control (FCTC) introduced guidelines for HWLs that Parties should implement, requiring that warnings cover at least 30% of the principal display areas of the pack and include pictures (World Health Organization, 2008). Article 11 also provides guidance on warning size, rotation, location, language and message content (World Health Organization, 2008).

The effectiveness of HWLs on tobacco packs is well documented: they increase knowledge of the harms of tobacco, (Kennedy et al., 2012; Hammond et al., 2006) increase intentions to quit and quit attempts among smokers, (Hammond et al., 2003; Azagba and Sharaf, 2013; White et al., 2008; Fathelrahman et al., 2009; Borland et al., 2009) prevent relapse in former smokers, (White et al., 2008; Partos et al., 2013) and prevent youth smoking initiation, (White et al., 2008) although some studies show mixed results (Noar et al., 2016). Compared to text-only warnings, pictorial warnings are more likely to be noticed, (Hammond et al., 2006; Hammond et al., 2003; Borland et al., 2009; Li and Grigg, 2009; Thrasher et al., 2007) be more effective in educating the public about the dangers of smoking, (Li and Grigg, 2009; Thrasher et al., 2007; Elton-Marshall et al., 2015) and increase intentions to quit (Hammond et al., 2006; Borland et al., 2009; Li and Grigg, 2009; Elton-Marshall et al., 2015; Hammond et al., 2007; Kees et al., 2011).

Globally, there is great variation in tobacco packaging and labeling requirements by country. At least 53 countries now require pictorial HWLs that cover 30% of the principal display areas of the pack (Campaign for Tobacco-Free Kids, 2015). Australia has implemented plain packaging with health warnings that cover 75% of the front of the pack and 90% of the back (Campaign for Tobacco-Free Kids, 2015). Nepal recently implemented pictorial warnings that cover 90% of the front and back of the pack (Campaign for Tobacco-Free Kids, 2015). Some Parties to the FCTC only meet minimal requirements — for

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instance, China and Japan require text warnings that cover only 30% of the front and back of the pack (Campaign for Tobacco-Free Kids, 2015).

Many studies have assessed compliance with smoke-free policies (clean indoor air laws) (Kumar et al., 2014; Park et al., 2013; Goel et al., 2014) and some have assessed compliance with tobacco advertising, promotion and sponsorship (TAPS) bans or restrictions (Mead et al., 2015; Salloum et al., 2013; Vardavas et al., 2013; Quedley et al., 2008). These studies provided evidence regarding loopholes in the law that need to be addressed, identified the need to improve or target enforcement efforts, and demonstrated compliance with the law. However, compliance with country-specific HWL requirements has been explored only minimally with very small sample sizes. One study examined 10 packs each from eight former Soviet Union countries (Mir et al., 2013); another inspected 5–18 packs from each of 12 countries (Mir et al., 2011). It is especially important to investigate compliance with country HWL requirements as tobacco companies are fully responsible for complying with HWL policies, as opposed to, for example, smoke-free legislation where responsibility is primarily placed on venue owners and staff. Evidence shows that tobacco companies have found ways to evade tobacco control interventions such as bans on misleading descriptors (Connolly and Alpert, 2014; King and Borland, 2005) and taxation (Collin et al., 2004; Lee and Collin, 2006; Legresley et al., 2008). Non-compliance with HWL best practices can result in poorer knowledge about the dangers of tobacco use, a reduction in quitting behaviors, and an increase in smoking initiation. Given that compliance is key to achieving the ultimate health goals of policy interventions, our research examined compliance with HWL requirements in 14 low-and-middle income countries.

2. Methods

We used a systematic protocol to collect packs and code HWLs (Smith et al., 2015). Briefly, cigarette packs were purchased in 2013 in the 14 low- and middle-income countries with the greatest number (count) of smokers: Bangladesh, Brazil, China, Egypt, India, Indonesia, Mexico, Pakistan, Philippines, Russian Federation, Thailand, Turkey, Ukraine, and Vietnam. To maximize the diversity of the sample of packs, we (1) chose the most populous city and two other cities [four additional cities in China] from the top 10 populous cities in the country, taking into account geographic location, ethnicity and religion; and, (2) within each city, selected 12 neighborhoods representing a range of high-, middle- and low- socioeconomic status (SES) as well as a range of ethnic, religious and other characteristics. In-country field staff used a variety of local and national sources, including census and property value data, to create a sampling frame of high-, middle- and low-SES areas for each city.

The protocol required the purchase of unique packs in one store in each of 36 neighborhoods per country. At the first store in the first city, one of every unique cigarette pack was purchased. In each subsequent neighborhood, we purchased any unique packs that we had not yet purchased. In total, we purchased 3307 unique packs (cigarettes, kreteks, bidis and straw cigarettes), ranging from 58 packs in Egypt to 505 in the Russian Federation (Smith et al., 2015).

Of the 3018 cigarette and 234 kretek (henceforth referred to as "cigarette") packs purchased (total n = 3252), 2478 (76%) had a HWL from the country in which the pack was purchased ranging from 19% in Pakistan to 100% in Brazil and Indonesia. Of these packs with a label from the country of purchase, 75% had a HWL that was in rotation at the time the purchase was made; this ranged from 21% in the Russian Federation to 100% in Bangladesh, Egypt, Indonesia, Philippines and Turkey, resulting in a sample of 1859 packs being evaluated for HWL compliance (Appendix 1). Soon after the packs arrived at our institution, the study team conducted an observational review of all the packs from a country at once; this allowed the identification of both patterns as well as unusual instances of packs and/or HWLs.

To assess compliance of each cigarette pack's HWL with country requirements, we developed a codebook for each country based on that country's requirements regarding cigarette HWLs. An example of a country HWL compliance codebook has been published (Smith et al., 2015); further examples are online (http://globaltobaccocontrol.org/tpackss/resources). Two coders used the codebook to independently code each pack that had a HWL in current rotation from the country in which the pack was purchased (n = 1859) for health warning compliance. Any discrepancies between coders were resolved by a third coder.

We applied up to four common indicators for HWL compliance that were pertinent to each country's requirements (if applicable): (1) health warning location (top, bottom, front and/or back); (2) health warning size (percent coverage); (3) health warning elements (e.g., text color, background color, borders); and, (4) health warning text size. We were able to apply the four common indicators to six countries: Bangladesh, China, Mexico, Pakistan, Philippines and Thailand. Eight countries did not have national requirements in place that corresponded with all four indicators and were therefore only assessed based on applicable indicators. The specific components of each indicator are described in Appendix 2. We assessed compliance with each applicable indicator. We also determined a summary measure of compliance: a HWL was determined to be compliant overall if it was compliant with all applicable indicator measures. Henceforth, "compliance" refers to when a HWL was compliant with all relevant compliance indicators (up to four) unless otherwise specified.

To estimate the level of inter-rater reliability for the binary variables, we assessed percent agreement as well as the prevalence-adjusted and bias-adjusted kappa (PABAK) statistic to account for the low prevalence of our binary outcomes (Cohen, 1960; Byrt et al., 1993; Lantz and Nebenzahl, 1996). For the continuous variables, including height and width of the pack and warning label area, and height of warning text, to the millimeter (mm), we used percent agreement as well as Krippendorff's alpha for interval data (Krippendorff, 1970; Hayes and Krippendorff, 2007).

We used descriptive statistics to examine the nature and extent of HWL compliance. We assessed compliance by country, SES of neighborhood, pack shape, stick count, parent company (five major transnational parent companies), and brand family (the five brands with highest frequency in our sample – brands from four of the five major transnational parent companies – plus the most common brand of the Korea Tomorrow & Global Corporation (KT&G)). All analyses were conducted using Stata 14 (StataCorp, 2015). To determine if there was bias introduced into our compliance estimates due to the protocol that required a large purchase at the first store – which often occurred in a high SES neighborhood – we also examined whether there was a difference in compliance for packs purchased in the first store compared to packs purchased in the other stores within a country. We used Pearson's chi-square tests to assess statistically significant differences. We also reviewed FCTC Article 11 Guidelines (World Health Organization, 2008) and compared countries' requirements for HWLs with those required and recommended by the FCTC implementation guidelines. Terminology such as each Party "shall adopt/shall require" or "should mandate/should address" or "should prohibit/should prevent" was interpreted as a requirement, whereas "should consider" was interpreted as a recommendation. We looked at requirements and recommendations for health warning label location, size, use of pictorials and color, rotation, message content, language, constituent and emissions reporting, and banning of misleading descriptors.

3. Results

3.1. Inter-rater reliability

Reliability of the coders' assessments was excellent (Appendix 3). For the binary variables, the average percent agreement was 99% and

the average PABAK was 0.98. The average agreement for continuous variables was 64% with a range from 59% to 81%. Even before the review session the average alpha statistic, 0.94, was >0.8 (the lower threshold for "almost perfect" reliability (Landis and Koch, 1977)) for all countries in the dataset.

3.2. Compliance

Overall, 72% of packs evaluated for HWL compliance complied with all of the relevant common indicators of HWL compliance (henceforth referred to as "health warning compliance" or "compliance"), ranging from 17% in the Philippines to 94% in Mexico (Table 1). There was 99% compliance in countries that specified the location of the HWL (e.g., top or bottom of pack, front or back panel). Of the four compliance indicators, size of the HWL (the minimum required coverage) showed the lowest compliance (i.e., the HWL was too small), ranging from 46% (Bangladesh) to 99% (China). Label elements (such as color contrast or content of warnings) showed 94% compliance overall, ranging from 80% in Indonesia to 100% in Brazil, Egypt, India, Mexico, Russian Federation, Thailand, Turkey, and Vietnam. For labels that specified a text size, compliance varied considerably across country; it was 26% in Philippines and 100% in Pakistan, Russian Federation and Vietnam. For the 514 packs that were non-compliant for at least one indicator, the percentage of packs with the same compliance decision between indicators ranged from 19% (size and label elements, n = 457) to 83% (location and label elements, n = 351).

Overall, compliance was greatest (79%) for packs bought in high SES neighborhoods (n = 870) and lowest (64%) for packs bought in low SES neighborhoods (n = 434) ($p < 0.01$). This result may be potentially confounded by the larger initial store purchases that were most likely to be made in high SES neighborhoods. A regression of compliance on initial store and SES found that both had a significant effect ($p < 0.05$). Even when the initial store purchase was excluded, compliance remained greatest (74%) for packs from high SES neighborhoods (n = 465) and lowest (61%) for packs from low SES neighborhoods (n = 312) ($p < 0.01$). Findings by country are shown in Appendix 4. The findings by neighborhood SES level, although not representative, are suggestive of a potential issue that could benefit from further investigation.

Overall, there was not a statistically significant difference in compliance by pack shape (traditional, wide, or narrow "lipstick"-style packs) but there were differences within countries. Within the nine countries that had more than one pack shape, wide packs (width:height ratio >2:3) were less likely to be compliant than traditional packs (width:height ratio approximately 2:3) in Mexico (71% vs. 98%; $p < 0.01$) and the Russian Federation (50% vs 92%; $p < 0.01$). Packs containing 10 cigarettes or fewer were less likely to be compliant than packs with >10 cigarettes (53% vs. 74%; $p < 0.01$). There was no difference in overall compliance between countries that required pictorial warnings versus those that did not. However, compliance was more likely in the 10 countries that required HWLs on both the front and back panels (76%) than in the four countries (Brazil, India, Indonesia, Philippines) that required HWLs on one panel (63%; $p < 0.01$).

Just over half (n = 1043; 56%) of the packs in our sample were manufactured by the top five multinational tobacco parent companies. HWL compliance varied across these companies: 49% of the packs from KT&G and its subsidiaries were not compliant compared to 32% from Imperial Tobacco Company (ITC), 30% from Philip Morris International (PMI), 21% from Japan Tobacco International, (JTI) and 19% from British American Tobacco (BAT) ($p < 0.01$) (Table 2). Not all countries had all the parent companies represented. Compliance by parent company varied across countries. In Brazil, 66% of packs from PMI and its subsidiaries were not compliant compared to 0% from BAT and its subsidiaries ($p < 0.01$). In Indonesia, 43% of packs from KT&G and its subsidiaries were not compliant, compared to 21% or less from the other four multinational companies ($p < 0.05$). In Pakistan, 40% of packs from PMI and its subsidiaries were not compliant compared to 5% from BAT and its subsidiaries ($p < 0.05$). In Turkey, ITC and its subsidiaries had the highest proportion of packs that were not compliant relative to the other parent companies (62%; $p < 0.05$). In Ukraine, all 10 packs from KT&G were not compliant, compared to 14% or less from the other companies ($p < 0.01$).

HWL compliance by the most common brands in our sample tended to mirror compliance by parent company. Overall, compliance was lowest for Esse (38%, KT&G) and was highest for Kent (94%, BAT); HWL compliance was 68% for Marlboro (PMI), 68% for Winston (JTI), 72% for Davidoff (ITC), and 85% for Camel (JTI) ($p < 0.01$).

3.3. Additional compliance-related issues

During observational reviews of the HWLs, we recognized that a number of countries had issues maintaining consistent coloring in their warning labels.

Mexico has very detailed requirements for their HWLs, but on some packs the yellow warning text on the front is outlined in black and on others it is not.

There were also differences in text warning size, font, and formatting across packs (including in the Philippines, Ukraine and Vietnam). We observed differences in aspect ratios which affected how the picture warnings appeared on the packs: in the Russian Federation some of the pictures appeared to be compressed so as to fit on the pack, and in Turkey part of the warnings were cut off on some packs.

We found that tax stamps often obstructed the HWL when labels were positioned at the top of the package.

3.4. Compliance by initial store

The study protocol involved purchasing all unique packs in the initial index store, and then purchasing only new unique packs in the remaining 35 stores in a country. For about half of the countries (six of 13 countries – no data for Brazil) compliance was not different for packs purchased in the index (first) store compared to packs purchased in all other stores in the country (Table 3). This suggests that, at least in six of the countries, the estimates of compliance were not influenced by the choice of the index store. For the remaining countries, that compliance was higher in the initial store may be because a larger store could be more likely to adhere to rules regarding the products they sell, or that packs with smaller market share are more likely to be found after multiple purchase attempts and be non-compliant.

Table 1
Health warning label compliance by indicator, by country, 2013.

Country	n	Compliance with all 4 indicators	Location	Size	Label elements	Text size
Overall (all countries)	1859	72%	99%	80%	94%	90%
Bangladesh	56	45%	75%	46%	93%	96%
Brazil	115	70%	100%	70%	100%	
China	352	90%	100%	99%	91%	99.7%
Egypt	55	73%		73%	100%	
India	75	80%	100%	80%	100%	
Indonesia	215	73%			80%	89%
Mexico	72	94%	100%	96%	100%	99%
Pakistan	67	58%	100%	64%	84%	100%
Philippines	99	17%	100%	68%	98%	26%
Russian Federation	106	90%		90%	100%	100%
Thailand	63	63%	98%	68%	100%	95%
Turkey	241	59%	100%	59%	100%	
Ukraine	260	78%		92%	95%	89%
Vietnam	83	73%		73%	100%	100%
Sample size		1859	1400	1644	1859	1373

Note: Cells are empty if a country does not have a requirement for the compliance indicator.

Table 2
Health warning label compliance by five multinational parent companies and their subsidiaries, by country, 2013.

Country	# of packs from the 5 co.'s	Philip Morris International	British American Tobacco	Japan Tobacco International	Imperial Tobacco Company	Korea Tomorrow & Global Corporation
Overall*	1043	70% (n = 346)	81% (303)	79% (236)	68% (123)	51% (35)
Bangladesh	22	100% (2)	75% (20)			
Brazil*	103	34% (50)	100% (53)			
China	33	100% (4)	100% (10)	100% (11)	100% (4)	100% (4)
Egypt	39	80% (15)	75% (16)		88% (8)	
India	1		100% (1)			
Indonesia*	53	100% (24)	79% (14)	100% (5)	100% (3)	57% (7)
Mexico	71	94% (34)	91% (23)	100% (13)	100% (1)	
Pakistan*	34	60% (15)	95% (19)			
Philippines	77	12% (41)	43% (7)	30% (23)	0% (5)	0% (1)
Russian Federation	88	100% (28)	93% (15)	88% (32)	92% (12)	100% (1)
Thailand*	31	89% (18)	0% (1)	100% (11)		0% (1)
Turkey*	225	70% (50)	58% (67)	65% (60)	38% (37)	100% (11)
Ukraine*	229	93% (58)	88% (41)	90% (71)	86% (49)	0% (10)
Vietnam	37	43% (7)	88% (16)	80% (10)	50% (4)	

Notes: The null hypothesis is that compliance is equal across all parent companies; the alternative hypothesis is that compliance is different between at least one pair of parent companies. Cells are empty if there were no packs from that parent company. In India, 64 out of the 75 packs coded for HWL compliance are from two brand owners: Godfrey Philips India Ltd. and Imperial Tobacco Calcutta. These companies are not subsidiaries of the top multinational tobacco parent companies, but do license brands such as Marlboro and Benson & Hedges.
* $p < 0.05$ for comparison of HWL compliance by company, within country.

3.5. Comparison to FCTC requirements

Ten of the 14 countries met the FCTC location requirement for a HWL on both the front and back of the pack, but only five countries met the recommendation to have a *pictorial* warning on both the front and back. Three countries required the HWL at the top of the pack, and only Thailand met the recommendation to have health warning messages on all panels and inserts/onserts. Indonesia was the only country to not meet the HWL size requirement to cover no less than 30% of the principal display area. All countries met the requirement for the HWL to appear in the country's principle language. Comparisons of country requirements to requirements and recommendations from the FCTC Article 11 Guidelines for implementation on these and other features can be found in Table 4.

4. Discussion

Our findings suggest that cigarette manufacturers are often not fulfilling all of their obligations regarding HWLs on cigarette packs. Compliance with HWL requirements was <90% in 11 of the 14 countries examined, with large variation in compliance across countries. Compliance in the Philippines was particularly low (17%), with the lack of compliance driven mostly by text size that was too small. That compliance varies by country may be due in part to the country's ability to enforce its laws more generally or the level of tobacco industry interference in a country.

There was high compliance for location of the warning but, overall, only 80% of HWLs met their country's size requirements, i.e., they were too small. This is very concerning especially given the preponderance of evidence that HWLs are more effective when they are bigger (e.g., Hammond, 2011).

Differences in compliance were found by socioeconomic status of the neighborhood where the pack was purchased, with higher compliance in higher SES neighborhoods. This is also concerning as it suggests that lack of compliance may exacerbate health disparities.

Further, overall compliance varied by parent company and brand family. Only half of packs manufactured by KT&G were compliant, but even BAT – which had the overall highest compliance – produced packs that were not compliant. While some of these non-compliant packs may be counterfeit, it is up to the manufacturers to protect their brand names and control the illegal supply of cigarettes.

Countries need to monitor on a regular basis whether manufacturers are adhering to HWL requirements, and hold manufacturers accountable when they do not.

While it is essential that HWLs comply with their country's requirements in order to maximize the public health impacts of HWLs, high compliance with policies that involve inadequate requirements is also a key issue to be addressed. As a case in point, there was very high compliance in China, but the Chinese HWL requirements are weak – the text-only warnings just meet the FCTC minimum coverage of 30%, and there are no specifications for either the color of the text or the color of the background of the warning. In practice, the health warning text color is often similar to the brand name text color, and the background of the warning also uses colors from the rest of the pack, making it difficult to distinguish between the warning and the rest of the content printed on the pack (Appendix 5). At a minimum, China should require black text on a white background or white text on a black background for the HWL. Moving to a higher coverage and pictorial warnings would also be better at informing people in China about the dangers of tobacco products.

Although we focused our coding of HWL compliance on each country's warning label specifications, we did observe other aspects related to implementation of the warnings. For example, in Brazil, the

Table 3
Compliance at initial store vs. all others, 2013.

Country	Initial store		All other stores		P value
	Overall compliance	n	Overall compliance	n	
Bangladesh	56%	32	29%	24	0.04
Brazil	–	–	–	–	–
China	90%	106	91%	246	0.77
Egypt	95%	19	61%	36	<0.01
India	73%	30	84%	45	0.24
Indonesia	100%	28	70%	187	<0.01
Mexico	93%	60	100%	12	0.36
Pakistan	100%	9	52%	58	<0.01
Philippines	0%	10	19%	89	0.13
Russian Federation	95%	61	82%	45	0.03
Thailand	63%	35	64%	28	0.91
Turkey	74%	90	50%	151	<0.01
Ukraine	91%	69	73%	191	<0.01
Vietnam	74%	47	72%	36	0.82
Total (all countries)	82%	596	67%	1148	<0.01

Note: Data on initial store were not available for Brazil. [1859 packs coded for HWC – 115 packs from Brazil = 1744 total packs].

Table 4
Comparison of FCTC Article 11 Guidelines requirements and recommendations to 2013 country requirements.

FCTC Requirements and Recommendations	Bangladesh	Brazil	China	Egypt	India	Indonesia	Mexico	Pakistan	Philippines	Russia	Thailand	Turkey	Ukraine	Vietnam
Location requirements														
Front and back	Y	N	Y	Y	N	N	Y	Y	N	Y	Y	Y	Y	Y
Top of PDA	N	N	N	N	N	N	Y	Y	N	N	Y	N	N	N
Opening does not damage/conceal HW	N	N	–	N	Y	N	Y	N	Y	Y	N	Y	Y	N
Location recommendations														
HW messages on all panels and inserts/onserts	N	N	N	N	N	N	N	N	N	N	Y	N	N	N
HW messages not obstructed by other required markings (e.g. tax stamp)	Y	Y	–	N	Y	N	Y	N	Y	N	–	Y	Y	N
Introduce innovative locations for messages (e.g. filter)	N	N	N	N	N	N	N	N	N	Y	N	N	N	N
Size requirements														
50% or more but no less than 30% of the PDA	Y	Y	Y	Y	Y	N	Y	Y	N	Y	Y	Y	Y	Y
Text of HW bold, legible font size, style/color enhancing visibility and legibility	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y
Size recommendations														
More than 50% coverage of PDA	N	N	N	N	N	N	N	N	N	N	Y	Y	N	N
If border required, exclude space dedicated to framing HW from the size of the HW itself	N	N	Y	N	N	N	N	N	N	N	N	N	N	Y
Pictorials requirements														
Includes pictures/pictograms in color	N	Y	N	Y	Y	N	Y	Y	N	Y	Y	Y	Y	N
Pictorials recommendations														
Pictorial on front and back	N	N	N	Y	N	N	Y	Y	N	N	Y	N	Y	N
Color requirements														
Full color pictorial HW	N	Y	N	Y	Y	N	Y	Y	N	Y	Y	Y	Y	N
Contrasting colors for background of text for text-based elements of warning	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y
Rotation requirements														
HW messages rotate by having multiple messages concurrently or setting date after which message content changes	Y	Y	N	Y	Y	N	N	Y	N	Y	Y	Y	Y	N
HW messages in a series be on an equal number of retail packages (e.g., each variant within the brand family)	N	N	N	N	N	N	Y	N	N	Y	N	Y	N	N
Rotation recommendations														
Two or more sets of warnings to alternate after a specified period, and have phase in period where both sets are used concurrently	Y	Y	N	N	Y	N	Y	Y	Y	Y	Y	Y	N	N
Message content requirements														
HW message addresses different issues related to tobacco use, in addition to harmful health effects (e.g., cessation, addictiveness, etc.)	N	Y	N	Y	N	N	Y	N	Y	Y	N	Y	Y	N
Message content recommendations														
Innovative messages (e.g., outcomes on environment, industry practices)	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Language requirements														
HW appear in the principal language or languages	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Constituents and emissions requirements														
Qualitative message about emissions and constituents	N	Y	N	N	N	N	Y	N	N	N	Y	Y	N	N
Misleading/deceptive packaging requirements														
Packaging must not promote terms, descriptors, signs that create false	N	Y	Y	Y	Y	N	Y	N	N	N	Y	Y	Y	N

Table 4 (*continued*)

FCTC Requirements and Recommendations	Bangladesh	Brazil	China	Egypt	India	Indonesia	Mexico	Pakistan	Philippines	Russia	Thailand	Turkey	Ukraine	Vietnam
impression that product is less harmful than others														
Prohibit display of figures for emission yields	N	N	N	N	N	N	Y	N	N	N	N	N	N	N
Prevent display of expiry dates	N	N	N	N	N	N	N	N	N	N	N	N	N	N

Notes: PDA = principle display area; – = uncertain.

warning must cover 100% of the back of the pack, but the picture warnings were developed to cover 100% of the back of a "standard" sized pack, and prohibit companies from changing the dimension of the warning labels; on packs that are larger than the "standard" size, the warnings often do not cover 100% (Appendix 5). This inconsistency in the applicability of the policy could be addressed by requirements for a standard pack size. Another example is the yellow text required by Mexico; outlining the yellow text in black makes the text much more visible.

We acknowledge some limitations of this study. While we used a rigorous and systematic protocol to purchase cigarette packs, the goal in our sampling strategy was to maximize the diversity of the packs obtained. The sample of packs was not weighted to account for prevalence of use of each brand variant. The Global Adult Tobacco Survey (GATS) and the Euromonitor produce estimates of prevalence of use or sale, respectively, by brand family, for many countries, but these data sources do not provide any detail with respect to use or sale by brand variant. Indeed, we found multiple brand variants per brand family in many countries (Kroart et al., 2015). Thus, the compliance rates we present here are for a diverse sample of unique packs and do not necessarily translate to compliance for the brands most often purchased or consumed in a country. Further, the packs were bought in three populous cities in each country; HWL compliance in other cities or in rural areas might be different. It is possible that some of the packs we purchased and coded for health warning compliance were counterfeit. Overall compliance was lower for packs identified as cheap whites (cigarettes manufactured by legitimate business enterprises with a large share of the production being sold without all applicable duties paid) (Ross et al., 2015) ($n = 130$) compared to other packs (63% vs 73%, $p < 0.05$). Lastly, the systematic protocol to purchase cigarette packs was used to maximize the diversity of packs obtained within a country and may not be representative of the diversity of packs that are available within neighborhoods with the same SES.

Despite these limitations, a key strength of the study is the large number and the diverse range of packs assessed for HWL compliance, across a large number of countries in five of the six WHO regions. Future research could explore whether there is adherence to country requirements regarding the distribution of HWLs across packs when there is more than one HWL in rotation. In addition, studies could examine how pack design features and marketing appeals on packs might detract attention away from the HWLs.

List of abbreviations

BAT	British American Tobacco
FCTC	Framework Convention on Tobacco Control
GATS	Global Adult Tobacco Survey
HW	health warning
HWL	health warning label
JTI	Japan Tobacco International
KT&G	Korea Tomorrow & Global Corporation
PMI	Philip Morris International
SES	socio-economic status
TAPS	Tobacco advertising, promotion and sponsorship
WHO	World Health Organization

Conflicts of Interest

None of the authors have any conflicts of interest to disclose.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at http://dx.doi.org/10.1016/j.ypmed.2016.10.006.

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